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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------|
| 10/663,555 | 09/16/2003 | Bruce Shull | 1718-0004 | 2589 |
| 28078 | 7590 | 10/17/2005 | | |
| MAGINOT, MOORE & BECK BANK ONE CENTER/TOWER 1111 MONUMENT CIRCLE INDIANAPOLIS, IN 46204 | | | EXAMINER WOOD, AMANDA P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,555

Applicant(s)

SHULL ET AL.

Examiner

Amanda P. Wood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/20/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 1-3 in the reply filed on 20 September 2005 is acknowledged. Claims 4-7 are withdrawn from consideration.

Response to Amendment

Applicant's amendment filed on 20 September 2005 is acknowledged. Claims 1-3 have been amended by applicant. Claims 4-7 have been cancelled. Claims 8-11 have been added by applicant.

Currently, claims 1-3 and 8-11 are pending. This office action is in response to applicant's Remarks and Amendments filed 20 September 2005.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor. Citizenship is missing for applicants Hyeon-Sook Lee Zeng and Gena Lynn Antonopoulos.

Applicants Hyeon-Sook Lee Zeng and Gena Lynn Antonopoulos have not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.

Also, the signature for applicant Hyeon-Sook Lee Zeng is missing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll et al (U.S. Patent 6,284,550).

Carroll et al teach the use of a test strip for measuring the amount of a suspected analyte in a fluid, such as whole blood, whereby a color change in the strip corresponds to the amount of analyte in the fluid. Carroll et al also teaches the use of a separating layer in a test strip device to remove red blood cells from whole blood (see, for example, column 2, lines 1-20, and 45-61). Further, Carroll et al teach the use of a reflectance meter to measure the amount of change in reflectance of the color on the test strip so that the end-point of the reaction can be determined. While Carroll et al discuss in detail the measurement of glucose by this method, they also state that by "modifying the chemical reagent solutions" used in the test strip, one can test for the presence and/or amount of such analytes as cholesterol (see, for example, column 2, lines 24-67).

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Claims 1-3 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldman (U.S. Patent 6,844,149 B2).

Goldman teaches a "multi-component test strip for analyzing a plurality of blood components in a single blood sample" (see, for example, column 12, lines 20-31). Goldman further teaches in the Abstract a multi-component test strip having a "sample receiving region" that is "fluidically in series" with two or more "sample analysis regions." In Claim 8, applicant claims a test strip having at least two "stacks." The term "stack" in its broadest reasonable interpretation, can be deemed a sample analysis region or pad, as described by Goldman (see, for example, column 12, lines 21-35). Goldman describes a test strip with two or more sample analysis regions. Furthermore, Goldman teaches the use of a layer or membrane to separate plasma from whole blood and another layer having reagents incorporated within that will produce a colored reaction in proportion to the concentration of the blood component tested for (see, for example, column 27, lines, 10-60). Among the specific blood components Goldman describes are cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol (see, for example, column 13, lines 1-10).

Additionally, with reference to Thakore et al, Goldman teaches that "precise...temperature controls are not necessary" because the method of using this dry test strip for cholesterol testing measures an end-point of the reaction (see, for example, Goldman, column 27, lines 30-60). Therefore, broadest reasonable interpretation of the phrase "precise...temperature controls are not necessary" can be interpreted to mean

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that a reaction may be practiced at room temperature, a limitation provided by applicant in Claim 2.

Therefore, the references are deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll et al (U.S. Patent 6,284,550) and Goldman (U.S. Patent 6,844,149 B2) in view of Nakamura et al (US Patent 6,764,828 B2).

The primary references are relied upon for the reasons set forth above. These references reasonably teach the use of colorimetric test strips having multiple layers for determining the amount of cholesterol (total cholesterol, HDL, and LDL) – as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result-effective adjustments of conventional working conditions and/or design-choice parameters within such blood cholesterol test strips/assays (e.g., using a particular end-point algorithm, and/or matrix design

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arrangement therein) based upon the overall beneficial teachings provided by the primary references.

None of the primary references expressly teach the use of a surfactant such as Emulgen B66 within such test strips.

Nakamura et al. teach the use of a surfactant such as Emulgen B66 that preferentially reacts with cholesterol in HDL's and VLDL's. Nakamura et al. further beneficially discloses that a cholesterol-assaying enzyme reagent used in the presence of a specific surfactant to HDL and VLDL actually accelerates the reaction of HDL and VLDL cholesterol and retards the reaction of LDL cholesterol (see, e.g., Abstract; col. 2, lines 325-67; and col. 3, lines 30-65). In addition, Nakamura et al. state that the reaction of HDL and VLDL cholesterol terminates prior to the reaction of LDL cholesterol – thus, adding a surfactant so as to facilitate the measurement of the reaction end-point to determine the amount of non-LDL cholesterol contained in the plasma tested would be clearly desirable.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include and/or substitute a surfactant such as Emulgen B66 that acts on HDL and other non-LDL cholesterol within cholesterol test strips such as those taught by the primary references (e.g., for assaying non-LDL levels) based upon the beneficial teachings provided by Nakamura et al. (as discussed above) – i.e., a surfactant that acts on HDL (e.g., Emulgen B66) or on other non-LDLs so that the non-LDL fraction of the blood sample plasma would react faster than the LDL fraction of

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the sample, based upon the art-recognized ability of a surfactant to aid in the quantification of specific lipoproteins.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is 571-272-8141. The examiner can normally be reached on M-F 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

APW



Amanda P. Wood
Examiner, AU 1655



CHRISTOPHER R. TATE
PRIMARY EXAMINER